ACTION: Final

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CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

 Agency Name:
 Ohio Board of Nursing

 Regulation/Package Title:
 Nursing Board Five Year Rule Review: OAC Chapters 4723-5, 4723-7, 4723-13 and 4723-27

 Rule Number(s):
 4723-5-01 through 4723-5-06, 4723-5-08 through 4723-5-17, 4723-5-19

 through 4723-5-21, and 4723-5-23 through 4723-5-25; 4723-7-01 through 4723-7-10; 4723-13

01 through 4723-13-03, and 4723-13-05 through 4723-13-07; and 4723-27-01 through 4723-

<u>27-10.</u>

Date: August 24, 2016

Rule Types: <u>Amended/No Change/New/5-Year Rule Review</u>

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language. Please include the key provisions of the regulation as well as any proposed amendments.

The Board proposes to amend, file new, or file no change rules following the five-year rule review for Ohio Administrative Code (OAC) Chapters 4723-5, Nursing Education Programs; 4723-7, Examination and Licensure; 4723-13, Delegation of Nursing Tasks; and 4723-27, Medication Administration by Certified Medication Aide.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Ohio Revised Code (ORC) Section 4723.07 ORC Section 4723.26 (Volunteer's Certificate, OAC Chapter 4723-7-10) ORC Section 4723.69 (Chapter 4723-27, OAC)

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? *If yes, please briefly explain the source and substance of the federal requirement.*

The answer is no to both questions as applied to all the rules in this package.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

The question is not applicable to this rule package.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The public purpose for the rule package is to actively safeguard the health of the public through the effective regulation of nursing education and practice. The rules are being updated consistent with the schedule for the Board's five-year rule review. Within that review, compliance, education and practice issues initiated the need for update, other change or to provide further clarity, including for technical or non-substantive reasons.

Recently enacted legislative amendments also required changes to rules. HB 188, 131st GA, effective March 23, 2016, amended the RN and PN license expiration date from September 1 to November 1 and that required several changes to Chapter 4723-7 rules.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

Success will be measured by having clear rules written in plain language, by licensee compliance with the rules, and minimal questions from licensees and the public regarding the

requirements of the rules.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

The Board convened a Committee on Practice on January 20, 2016 to review whether the Board needed to adopt any rules regarding APRN delegation of medication administration to unlicensed personnel.

The Board discussed the rules package at its public Board meetings in April, May and July 2016. Board meeting dates and agendas are posted on the Board's website and interested parties are sent notice by e-mail prior to the meeting. At the April Board meeting, the Board reviewed recommendations for Chapter 4723-5 rule changes provided by the Advisory Group on Nursing Education at its February 23, 2016 and previous meetings (see dates below). At the May Board meeting, the Board reviewed recommendations submitted by the Ohio Council of Deans and Directors of Baccalaureate and Higher Degree Nursing Programs; Muskingum University; Brown Mackie College; and individual educators, related to Chapter 4723-5.

The Board held an interested party's meeting with multiple stakeholders on May 26, 2016. Participants and invitees included representatives of the Ohio Nurses Association (ONA), the Ohio Association of Advanced Practice Nurses (OAAPN), Council for Ohio Health Care Advocacy (COCHA), the Licensed Practical Nurse Association of Ohio (LPNAO), the Ohio Council of Deans and Directors of Baccalaureate and Higher Degree Nursing Programs (OCDD), the Ohio Organization of Practical Nurse Educators (OOPNE), and the Ohio Council for Associate Degree Nursing Education Administrators (OCADNEA). Notice and invitation to the meeting was sent by e-mail on April 27, 2016 to approximately 40 persons representing various stakeholders to the Board.

The Board's Advisory Group on Nursing Education met at the Board office in October 2014, February 2015, June 2015, October 2015, February 2016 and June 2016, and discussed nursing education issues and possible amendments for consideration that concerned nursing education rules in this package. The Nursing Education Advisory Group has membership that includes Board members who are administrators and educators in nursing programs and non-Board members who hold similar positions and are members of various education program associations. Meetings are scheduled by e-mail and are open to the public.

The Board hosted a Program Administrator Workshop for administrators and faculty of existing nursing education programs on June 10, 2016. Approximately 80 persons attended

the Workshop. Board staff reviewed the draft rules for Nursing Education Programs with the participants at the Workshop. The Board's Advisory Group on Continuing Education also reviewed the proposed rules on June 17, 2016.

8. What input did the stakeholders provide, and how did that input affect the draft regulation being proposed by the Agency?

The majority of input from stakeholders concerning rules in this rules package involved the rules in Chapter 4723-5 that govern nursing education programs. Key stakeholders in the review of this chapter include the Board's Advisory Group on Nursing Education and various associations representing nursing programs and educators. Discussions of these rules took place at various times and in a variety of settings over the past year or two. The result of these discussions, along with opinions expressed by individual educators, resulted in the proposed rules following the review process. Board staff believes that interested party and meeting discussions have resulted in a comprehensive understanding among stakeholders, and stakeholder acceptance of the rationale for Board rule proposals in Chapter 4723-5. It should also be noted that the Board has five members who are actively involved in nursing education, either as nursing education faculty or administration. Without addressing each point of discussion as it related to changes that clarified language, required technical language revision or response to recent changes in statute, stakeholder input and the effect on Board decisions may be summarized as follows:

Rule 5-01: At its April 2016 meeting, the Board defined "Patient simulation" to mean the replication of a real world patient in situ through accurate representations of patient cues and stimuli that a student is to observe, analyze, interact, and respond to with right nursing judgments and actions. The replication may be provided through the use or combination of standardized patients, computerized sophisticated patient models or mannequins, and related software programs.

The Board also reviewed both long and short definitions of "high fidelity", "mid or moderate fidelity" and "low fidelity" and decided to include the shorter versions of the definitions in the rule. The Board agreed with the language included in the rule that was drafted and discussed with input from the Nursing Education Advisory Group.

Rule 5-09(A)(2): OCDD submitted a rationale as to why it would like the Board to reconsider removing the words "and students" from the proposed language focused on how faculty and students are involved in determining academic and program policies and procedures, planning curriculum, and program evaluation. Consistent with discussion in the Nursing Education Advisory Group, the Board in response stated that the rule does not specify how students are to be involved in curriculum planning, so they believe the rule is broad enough to assure student involvement but to allow each education program to

determine how to involve students in the process. Board surveyors over the years have not identified student involvement in accordance with this rule as an issue. The Board agreed not to change the language in the current rule.

Rule 5-09(D)(2): OCDD requested that the Board further define what absence of a program administrator means, i.e., vacation, illness, termination; OCDD also asked for clarification regarding "physical presence vs. contact by phone or mail." The Board noted that termination and vacancies are addressed elsewhere in the rule. The Board also noted that there could be reasons for absences other than vacation or illness, such as jury duty, personal leave, etc., so it would be difficult to list all the reasons, and did not want the rule to become overly prescriptive. The Board discussed that if the program administrator was present by telephone or email, such as working at a home office, then the employer would decide if this constitutes an absence. The Board decided not to make any revisions.

Rule 5-10(A)(5)(b): OCDD requested that the Board "consider one year of nursing practice with demonstrated competency for those nurses who have at least a BSN to be an appropriate preceptor" instead of experience for at least two years in the practice of nursing. The Board stated they believe two years of experience provides a better assurance that the preceptor is experienced in the type of practice and work setting in which the nursing student is precepted. The Board agreed to keep the requirement of two years experience.

Rule 5-11(A)(2): In November 2013 Brown Mackie College requested that the Board consider changing minimum requirements for a PN program associate administrator, so that two years of experience can include "teaching in the clinical or laboratory setting" instead of being limited to serving as a "faculty member." The Advisory Group on Nursing Education recommended that the current minimum requirements not be changed, and the Board agreed not to change this rule.

Rule 5-12(B): The Board declined a request from a nursing program to create an "appeal process" for programs that want to change their program content/curriculum as to currently enrolled students. In making this determination, the Board noted that increased flexibility for program curriculum is reflected in the Board's recommended changes to Rules 5-13 and 5-14 that will allow programs to interchange clinical and laboratory hours within a course.

Rule 5-13(F)(8) & Rule 5-14(E)(12): The Advisory Group on Nursing Education and OCDD recommended new language to allow simulation within certain levels of "fidelity" to replace clinical experience in obstetrical/immediate newborn care. The Board agreed to this language, and also added language authorizing the use of simulation for pediatrics. The Advisory Group recommended expanding the operation of patient simulation to include

"teaching assistants." The language has been revised to encompass teaching assistants, and also to clarify, based on comments received at the interested party meeting, that computer technology specialists may assist in operating computer equipment.

Rule 5-13(F)(7) & Rule 5-14(E)(2): Based on a request from an educator submitted in November 2015, the Board added language to the minimum curriculum that specifically address "gender identity, sexuality" as related to an understanding of the patient's health status. In addition, in Rule 5-13 the Board accepted a request from a former Dean of a nursing program to add "humanities" to the required curriculum content, as it relates to an understanding of the patient's health status. The Board also approved proposals by OCDD to include a reference to nursing informatics," and their request that the manager of care content include "prioritization and resource allocation"; but the Board agreed, however to retain the reference to "physics" rather than the proposed change to "body mechanics."

Rule 5-13(E)(1): The current rule requires "twelve months" of clinical nursing coursework; the Board is proposing to change this to 45 weeks. On June 6, 2016 OCADNEA requested that the Board change this to something less than 45 weeks; on July 7, OAC also requested a lesser time period. As discussed by the Advisory Group on Nursing Education, Board staff explained that for associate degree programs and associate degree programs that are one plus one programs the 45 week period applies to the *total* two-year curriculum; each year of the one plus one program is not a separate curriculum requiring 45 weeks. The Board agreed to keep the proposed 45-week language in the rule.

Rule 5-21(A): The language was revised, based on input received at the interested parties meeting to state that records should "reflect the student's achievement of the specific behavioral and cognitive skills" rather than reflect the student's "progress."

Rule 5-23(B): The Board discussed that some who complete nursing education programs do not take the NCLEX for the first time until years later, regardless of the amount or type of encouragement provided. NCSBN data shows that first time test takers are more successful in passing the NCLEX if they take the test within six months of completing the education program. The Board agreed to add language limiting NCLEX pass rate calculations to those who took the examination within six months of completion of a program.

Rules 7-03(G): The Board decided that rather than adopting the suggestion to rescind the paragraph, which states the Board shall send reports of the (NCLEX) testing results to nursing education programs, the language be changed from "shall" send to "may" send.

Rule 7-09: Recently, the Department of Administrative Services (DAS) implemented a new online licensing system (eLicense 3.0). The Board was advised in June 2016 that the new system was not set up to enable different expiration dates for the primary (RN) license versus the "endorsement" license (COA, CTP). Historically, rule language for licensees, COA, and CTP holders has provided that if a license or certificate is first issued after March 1, the expiration date is the end of the subsequent renewal period. In other words, if a license is first issued after March 1, the individual is not required to renew that year. This is reflected in Rule 7-09 (RN/PN/COA).

The rationale has been that someone should not have to incur a renewal fee when they have recently been issued a new license or certificate. DAS advised that with respect to COA and CTP holders that are newly issued, the eLicense 3.0 system needs to have the certificate expiration date match the RN expiration date. To resolve this problem, staff agreed to recommend a rule change so newly issued (July 1 or after) COA/CTP certificates will expire on November 1, and thus, will be subject to renewal, but the renewal fee will be waived. ORC Section 4723.08(A) states that the Board "may" impose renewal fees but does not state the Board "shall", thus, the Board has the authority to waive these fees. DAS has indicated that it will provide an online renewal application for these groups that does not include a fee payment requirement.

Rule 13-05: The Board made changes to this rule because SB 110 (131st GA), effective October 15, 2015, amended Section 4723.48, ORC, by adding (C)(1) authorizing APRNs to delegate the administration of drugs (that are not controlled substances) to persons not otherwise authorized to administer drugs. Section 4723.489, ORC was added to set forth the conditions required for persons to be delegated this authority, including a requirement that the person "has successfully completed education based on a recognized body of knowledge concerning drug administration and demonstrates to the person's employer the knowledge, skills and ability to administer the drug safely."

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The Board convened a Committee on Practice on January 20, 2016 to review whether the Board needed to adopt any rules regarding APRN delegation of medication administration to unlicensed personnel. Commentators requested that rules be promulgated specifying what kind of education or certification would meet the statutory language (e.g., certified medication assistants would be recognized). The Board agreed by general consensus at the January meeting that no information, other than a reference to Section 4723.489, ORC, is needed in the rules since the statute specifies the requirements for APRN delegation of medication administration.

Through the Advisory Groups, the Board relied on the expertise of education providers, program administrators, nurses, and others based on their current practice experience and familiarity with current data in their areas of expertise. Chapter 4723-5 rules that permit greater use of simulation in nursing education, and specify types of technology in terms of levels of fidelity, is derived from evidence-based research in nursing education and practice.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

The Board did not consider other regulatory alternatives in this rule package based on its duty to carry out its public protection mission, and in part because certain rule revisions require updating or amendment related to statutory requirements, or for technical or non-substantive reasons.

11. Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

In most instances, the Board did not propose performance-based regulations in this rule package due to considerations of setting established processes and standards to achieve its public protection mandate. However, in Rule 4723-13-05, the Board chose not to specify what kind of education or certification would meet the new statutory allowance for APRNs to delegate medication administration to unlicensed persons.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

Because the Board initiated the rule review process due to the five-year rule review requirement, staff reviewed the rules with a focus on eliminating obsolete, unnecessary, and redundant rules and avoiding duplication. In addition, meetings with interested parties and Board Advisory Groups helped ensure that these rules do not duplicate any existing Ohio regulation.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

Meetings with interested parties and Board Advisory Groups help ensure that these rules are applied consistently and predictably for the regulated community. The Board plans to monitor the progress with respect to the rules and report back to these groups. In addition, the Board will implement the regulations while using its website, newsletter, and social media to update and inform licensees, continuing education providers, nursing education and training programs, other stakeholders, and the public in general. Licensees and applicants must also complete at least one hour of continuing education on Ohio law and rules as a required part

of their licensure application and subsequent licensure.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

Nursing students, individuals licensed by ORC Chapter 4723, nursing education and medication aide training programs, certified medication aides, health care employers and other entities.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance);

Pre-licensure nurse education programs are required to be approved by the Board. Individuals are required to have a license and meet various conditions for licensure, and to renew licenses.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

There is a cost inherent in engaging in the business of being a Board approved nursing education program or medication aide training program. That cost is variable and determined by the extent or degree of the program's management. Separate costs to obtain accreditation are not established by the Board. There is no fee attached to Board approval and the application process and forms are intended not to be burdensome.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

Baseline curriculum, faculty and other requirements are needed to be a Board approved nursing program or certified medication aide training program; these minimum requirements

are necessary for the education to meet educational standards and ensure public safety. The regulatory intent justifies the impact on business because it is critical to the Board's mission to ensure that nursing education and medication aide training programs operate under consistent standards and that they provide updated information to their students and the Board in the event of any significant operational change.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Public safety requirements relative to the rules reviewed in this package require consistency in their application to all licensees and education/training programs, and are not amenable to exemptions or alternative means of compliance for small businesses.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Waivers of fines and penalties for paperwork violations and first time offenders may be considered consistent with Sections 119.14 and 4723.061, ORC, which do not require the Board to act on minor violations of the Nurse Practice Act or the rules adopted under it, if applicants or individuals licensed under Chapter 4723 of the Revised Code commit violations and following review the Board determines that issuing a notice or warning to the alleged offender adequately protects the public.

18. What resources are available to assist small businesses with compliance of the regulation?

The Board employs staff dedicated to assist the public and small businesses by responding to any questions or concerns about the implementation of the rules. The Board Advisory Groups also may respond to questions from small businesses. The Board continues to use its website, newsletter and social media to regularly update the public and licensees, including small businesses, to changes in requirements and to provide frequently asked questions.